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Research Protocol

Anaesthesia Section

Effect of Infusion of Dexmedetomidine on Succinylcholine-induced Fasciculation and Myalgia in ENT Surgeries: A Research Protocol

KOLA KAVYA PRANEETHA[1], JAYASHREE SEN[2]

ABSTRACT

Introduction: Succinylcholine, a depolarising neuromuscular blocker, is widely used to facilitate rapid sequence intubation due to its rapid onset and short duration of action. However, it is associated with adverse effects, including transient elevations in Intraocular Pressure (IOP), which can be harmful in patients with ocular trauma or glaucoma.

Need of the study: Several pharmacologic agents have been studied to attenuate these IOP changes, with mixed efficacy and potential side-effects. Dexmedetomidine, a selective α2-adrenergic agonist with sedative, analgesic, and sympatholytic properties, has shown promise in attenuating sympathetic responses during laryngoscopy and intubation. Therefore, further investigation is warranted in this clinical setting.

Aim: To evaluate the efficacy of dexmedetomidine premedication in reducing succinylcholine-induced fasciculations and myalgia during general anaesthesia in patients undergoing elective Ear, Nose and Throat (ENT) surgeries.

Materials and Methods: The present randomised, double-blind control trial will be conducted in the Department of Anaesthesia, Acharya Vinoba Bhave Rural Hospital, a unit of Jawaharlal Nehru Medical College (DMIHER), Sawangi, Wardha, Maharashtra, India, over a period from July 2024 to June 2026. The study will include patients scheduled for elective surgeries under general anaesthesia. Patients will be randomly assigned to one of two groups: the study group, which will receive intravenous dexmedetomidine premedication (0.5 µg/kg), and the control group, which will receive normal saline. Standard anaesthesia protocols will be followed in both groups, and succinylcholine will be administered to facilitate intubation. IOP, Heart Rate (HR), and blood pressure will be recorded at baseline, after study drug administration, after succinylcholine injection, and following intubation. Data will be analysed using t-test, Chi-square test, and repeated-measures Analysis of Variance (ANOVA), with $p<0.05$ considered significant.

Keywords: Anaesthesia, Analgesics, Ear, nose and throat, Intravenous, Sympatholytics

INTRODUCTION

Succinylcholine (suxamethonium) is a depolarising neuromuscular blocking agent widely used during rapid sequence intubation and surgical procedures because of its rapid onset of action (30-60 seconds) and short duration (4-6 minutes), making it ideal for situations requiring quick and transient muscle relaxation [1]. It acts as an acetylcholine receptor agonist at the neuromuscular junction, causing transient muscle fasciculations followed by flaccid paralysis until it is rapidly hydrolysed by plasma cholinesterase [2]. Despite its advantages, succinylcholine is associated with adverse effects such as Postoperative Myalgia (POM), hyperkalemia, malignant hyperthermia, increased intraocular and intracranial pressure, and prolonged apnea in susceptible individuals, which limit its use in some patient populations [3].

Various strategies have been trialled to prevent succinylcholine-induced fasciculations and POM, such as precurarisation with low-dose non-depolarising muscle relaxants (e.g., rocuronium, cisatracurium), lidocaine, Non-steroidal Anti-inflammatory Drugs (NSAIDS) and magnesium, lidocaine [4-7].

Precurarisation can markedly reduce fasciculations- rocuronium at 0.06 mg/kg reduces fasciculations and biochemical markers like serum potassium and myoglobin-but may inadequately prevent myalgia and can delay the onset of succinylcholine or cause mild muscle weakness [8,9].

Succinylcholine-induced fasciculations are best prevented with non-depolarising muscle relaxants, lidocaine, or magnesium, while myalgia is best prevented with muscle relaxants, lidocaine, or NSAIDs; however, the associated risk of adverse effects, especially with muscle relaxants, is significant, and comprehensive risk-benefit data for alternative agents are lacking [10]. Lidocaine is beneficial but has dose-related toxicity [11]. NSAIDs offer partial relief with Gastrointestinal (GI)/renal risks [12], and magnesium may cause hypotension and neuromuscular prolongation [13]. No method has proven universally effective without adverse effects, underscoring the need for a safer, more reliable intervention.

Despite the availability of various pharmacologic strategies- such as non-depolarising muscle relaxants, lidocaine, magnesium, and NSAIDs- for reducing succinylcholine-induced fasciculations and myalgia, none of these interventions is both fully effective and free of significant adverse effects, such as respiratory weakness, blurred vision, hypotension, or gastrointestinal toxicity [10]. The dose-dependent risks and lack of robust risk- benefit data underscore the need for a safer, well-tolerated, and consistently effective intervention to mitigate these distressing side-effects without compromising patient safety or comfort.

Dexmedetomidine, a highly selective α2 adrenergic agonist, exerts sedative, analgesic, and sympatholytic effects by reducing sympathetic outflow and norepinephrine release-leading to central analgesia and skeletal muscle relaxation. It has been shown to lower postoperative pain and decrease opioid requirements in multiple surgical settings [14], and it effectively prevents postoperative shivering by modulating central thermoregulatory pathways [15]. These combined attributes, muscle relaxation, analgesia, and control of stress responses, make dexmedetomidine a compelling candidate for reducing succinylcholine-induced fasciculations and POM.

REVIEW OF LITERATURE

The use of succinylcholine, a depolarising neuromuscular blocker, is common in rapid sequence intubation and surgical procedures due to its rapid onset and short duration of action. However, it is often associated with undesirable side-effects such as fasciculations and POM, which can cause significant patient discomfort [10].

Celebi N et al., conducted a randomised controlled trial on 60 patients undergoing direct laryngoscopy to evaluate the effects of dexmedetomidine on succinylcholine-induced fasciculation, myalgia, and Creatine Kinase (CK) levels and demonstrated that dexmedetomidine significantly reduces the severity of succinylcholine-induced fasciculations and early POM compared with saline. Patients receiving dexmedetomidine showed better intubation conditions and a smaller postoperative rise in CK levels, indicating reduced muscle injury. Overall, dexmedetomidine improved peri-intubation conditions and attenuated succinylcholine-related side-effects [16].

Similarly Xue-hu S et al., concluded that pre-induction dexmedetomidine provided better hemodynamic stability during airway manipulation and surgery. It reduced the severity of succinylcholine-induced fasciculations and significantly decreased POM scores at 24 hours. Although fasciculation incidence and intubation conditions were similar between groups, dexmedetomidine clearly provided symptomatic benefit and cardiovascular control [17].

Sriramka B et al., conducted a randomised controlled trial on 100 patients aged 18-65 years undergoing electroconvulsive therapy to evaluate the effect of dexmedetomidine on succinylcholine-induced myalgia and fasciculations and found that a low dose of dexmedetomidine substantially decreased the incidence of succinylcholine-related myalgia and fasciculations during ECT procedures. Importantly, this benefit was achieved without causing any significant haemodynamic changes, highlighting dexmedetomidine's efficacy even at a modest dose [4].

The past literature findings demonstrate that dexmedetomidine effectively reduces the incidence and severity of succinylcholine-induced fasciculations and POM, while also improving haemodynamic stability and intubation conditions. These findings support its role as a safe and promising prophylactic agent in patients undergoing procedures requiring succinylcholine. Therefore, there is a need to explore safer and more effective agents, such as dexmedetomidine, that may also offer additional benefits like haemodynamic stability and improved intubation conditions.

The present study aimed to evaluate the effect of intravenous infusion of dexmedetomidine on the incidence and severity of succinylcholine-induced fasciculations and POM in patients undergoing general anaesthesia for ENT surgeries.

Primary objective: To determine the efficacy and safety of infusion of dexmedetomidine on succinylcholine-induced fasciculation and myalgia.

Secondary objective: To evaluate the haemodynamic variations to infusion of dexmedetomidine during laryngoscopy and endotracheal intubation.

Null Hypothesis (H_0): Dexmedetomidine infusion has no effect on the incidence or severity of succinylcholine-induced fasciculations and myalgia.

Alternative Hypothesis (H_1): Dexmedetomidine infusion reduces the incidence and/or severity of succinylcholine-induced fasciculations and myalgia.

MATERIALS AND METHODS

The present randomised, double-blind, controlled study will be conducted in the Department of Anaesthesia, Acharya Vinoba Bhave Rural Hospital, a unit of Jawaharlal Nehru Medical College (DMIHER), Sawangi, Wardha, Maharashtra, India, over a period from July 2024 to June 2026. Approval from the Institutional Ethics Committee with reference number DMIHER(DU)/IEC/2024/191 has been obtained prior to commencement of the study. Written informed consent will be obtained from all participants after appropriate counselling before enrolment. The study is registered in the Clinical Trial Registry of India with registration number. CTRI/2025/07/091816.

Inclusion criteria:

- Physical status I and II according to American Society of Anesthesiologists (ASA);
- Age between 18 years and 65 years;
- Weighing between 40-80 kg;
- Scheduled for elective short duration surgeries under general anaesthesia.

Exclusion criteria:

- Obesity, with body mass index >35 kg/m^2,
- With any such conditions as co-morbidities, hypertension, ischemic heart disease, diabetes mellitus, impaired kidney or liver functions, hyperkalemia, dehydration, increased intracranial or IOP, history of seizures, history of sleep apnea
- Anticipated difficult airways according to LEMON criteria
- Pregnant, currently breast-feeding women
- Patients with neuromuscular disease
- Contraindication to dexmedetomidine
- If the tracheal intubation cannot be performed at the first attempt/within 30s.

Sample size calculation:

$n=(Z\alpha/2 + Z\beta)^2 * (2 * \sigma^2)/\Delta^2$

Where:

- n=required sample size per group
- $Z\alpha/2$=Z-value for a confidence level of 95% (1.96)
- $Z\beta$=Z-value for power of 80% (0.84)
- σ=Standard deviation (11.90) [18]
- Δ=Minimum difference to be detected (15% of 71.37=10.70)

Calculation:

$n=(1.96 + 0.84)^{2*} (2* 11.90^2)/(10.70)^2$

$n\approx23$ per group

Considering 30% drop out for the study, the final will be 30 participants per group

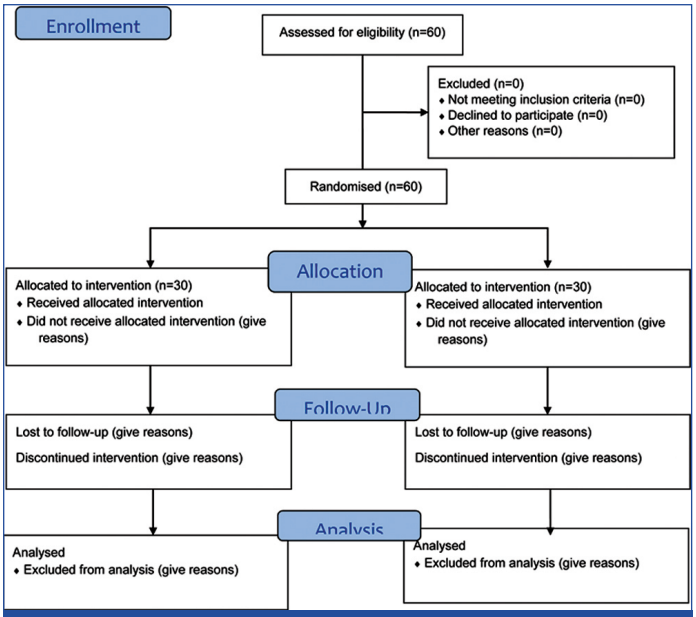
Patients scheduled for elective short-duration ENT surgeries under general anaesthesia will be included and randomly allocated into two equal groups (n=30 each) using computer-generated randomisation [Table/Fig-1]. Patients and the anaesthesiologist assessing outcomes will be blinded to the treatment allocation. Randomisation will be performed using computer-generated randomisation, ensuring an unbiased assignment of participants to either Group D (dexmedetomidine) or Group S (saline). Allocation concealment will be achieved by using opaque, sealed envelopes that are opened only after patient enrollment to prevent foreknowledge of group assignment, thereby minimising selection bias.

Group D: Patients will receive intravenous dexmedetomidine 0.5 µg/kg diluted in 20 mL normal saline, administered over 10 minutes.

Group S: Patients will receive 20 mL of normal saline intravenously, administered over 10 minutes [19].

Study Procedure

All patients will undergo detailed history, physical examination, and standard preoperative investigations {Complete Blood Count (CBC), urea, creatinine, blood sugar, blood grouping/typing, Electrocardiogram (ECG), chest X-ray, Hepatitis B surface Antigen (HBsAg)}. They will be kept nil per oral for six hours before surgery and will not receive any hypnotic premedication the previous night.



[Table/Fig-1]: CONSORT flow diagram.

On arrival to the operating theatre, an 18G intravenous cannula will be placed, and Ringer's lactate (10-15 mL/kg) will be started. Standard monitors- ECG, SpO_2, non-invasive blood pressure, and end-tidal CO_2 - will be attached. After infusion of the study drug over 10 minutes, patients will be premedicated with i.v. glycopyrrolate (0.2 mg), midazolam (0.04 mg/kg), and fentanyl (2 µg/kg). Anaesthesia will be induced with i.v. propofol (2 mg/kg). After confirming loss of verbal response and eyelash reflex, i.v. succinylcholine (2 mg/kg) will be administered to facilitate endotracheal intubation. One minute after succinylcholine, visible muscle fasciculations will be observed, and their duration and severity will be assessed by a blinded anesthesiologist. Intubation will be performed under direct laryngoscopy within 30 seconds. Anaesthesia will be maintained with 50% oxygen, 50% air, and isoflurane (1.6-2%). Muscle relaxation will be maintained with vecuronium (0.08 mg/kg) and supplemented as required. Intravenous fluids and mechanical ventilation will be provided as needed. At the end of surgery, neuromuscular blockade will be reversed with i.v. neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg), and patients will be extubated after meeting standard recovery criteria [20].

Outcomes

The POM is defined as pain in skeletal muscle not attributable to surgical intervention. Fasciculations will be graded as follows, according to Mingus ML et al., [21]

0 - (No fasciculation)

1- Mild (fine fasciculation at the eyes, neck, face or fingers without limb movement)

2- Moderate (fasciculation on both sides and obvious limb movement)

3- Severe (widespread, sustained fasciculation)

The degree and severity of myalgia, not related to surgical intervention, will be assessed and graded by a resident anaesthesiologist who is blinded to the group allocation, at the 30th and 45th minutes after extubation, while the patient is in the postoperative care unit. Grading will be performed as per the criteria described by Harvey SC et al., [22].

Myalgia will be graded as follows, according to Harvey SC et al., [22]:

0 - No muscle pain.

1 - Mild: muscle stiffness or pain in one area only, no treatment required.

2 - Moderate: muscle pain or stiffness reported by the patient, requiring treatment.

3 - Severe: generalised, severe pain requiring additional treatment.

The adequacy of relaxation for intubation will be evaluated as:

- Satisfactory: Well-relaxed, no patient movement during intubation.
- Fair: Vocal cords not moving, minor patient movement.
- Poor: Vocal cords moving, with obvious patient movement, bucking, or coughing during intubation [23].

The following parameters will be recorded in both groups at specified time points: HR, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Mean Arterial Pressure (MAP):

1. T1: before administration of the study drug (baseline).
2. T2: 10 minutes after administration of the study drug.
3. T3: 1 minute after succinylcholine injection.
4. T4: 1 minute after intubation.
5. T5: 3 minutes after intubation.
6. T6: 6 minutes after intubation.

Side-effects such as hypotension (fall in SBP>20% of baseline), bradycardia (HR<40 beats/min sustained for one minute), or hypotension (MAP<60 mmHg) will be assessed intra-and postoperatively.

STATISTICAL ANALYSIS

All collected data will be analysed using SPSS version 21. Descriptive statistics will be performed to summarise the data: continuous variables such as HR, SBP, DBP, and MAP, duration of fasciculations, and duration of myalgia will be presented as mean ± standard deviation or median with interquartile range, as appropriate. Categorical and ordinal variables such as grades of myalgia, grades of fasciculations, adequacy of intubation, and incidence of adverse events will be expressed as frequencies and percentages. The normality of continuous variables will be assessed using the Shapiro-Wilk test. If the data are normally distributed, an independent Student's t-test will be used to compare means between the two groups; if not normally distributed, the Mann-Whitney U test will be applied. Categorical and ordinal variables will be compared using the Fisher's exact test or the Chi-square test, as appropriate. A p-value <0.05 will be considered statistically significant.

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PARTICULARS OF CONTRIBUTORS:
1. Junior Resident, Department of Anaesthesiology, JNMC Sawangi, Wardha, Maharashtra, India.
2. Professor, Department of Anaesthesiology, JNMC, Sawangi, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Kola Kavya Praneetha,
Junior Resident, Jawaharlal Nehru Medical College, Sawangi, Wardha, Maharashtra, India.
E-mail: kolakavyapraneetha@gmail.com

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